

INFORMATION Notice 2020 – 02; issued 8/03/2020

Notice of Proclamation of Disaster Emergency due to COVID-19 on July 24, 2020 as it relates to Iowa Mammography and Stereotactic regulations

A proclamation issued by the State of Iowa (SIA) governor on July 24, 2020 temporarily suspends the regulatory provisions of Iowa Code 136C until August 23, 2020. This includes continuing experience for mammography and stereotactic personnel (radiologist/physicians, technologist, and physicist). This does **not** apply to initial or requalification. The SIA is making the following provisions, each with their own expiration date.

[Proclamation of Disaster Emergency issued 7/24/2020](#) - Iowa Code 136C reference

Mammography – continuing experience effective until 12/31/2022

The SIA rules for personnel qualifications (radiologists, technologist and medical physicist) are more stringent than the FDA and requires individuals to maintain continuing qualifications at all times while performing mammography. In comparison, the FDA only requires facilities to demonstrate each individual's compliance with continuing qualifications on the date of inspection. **Due to the COVID-19 pandemic, SIA is removing the more stringent requirements on personnel qualification (radiologists, technologist and medical physicist) through 12/31/2022. Mammography facilities will only need to prove each meets the requirements on the day of inspection.** This will help alleviate the void of continuing experience numbers caused by COVID-19.

The above temporary provision is in lieu of the SIA's regulations which state mammography personnel needs to meet the continuing requirements whenever interpretations are performed by the physician, whenever mammogram procedures are performed by the radiologic technologist, and whenever medical physics services are provided by the medical physicist.

Mammography – annual medical physicist survey

The SIA is aligning with FDA's regulatory flexibility due to COVID-19 on medical physicist surveys. For mammography facilities in which the annual medical physicist survey falls within the time period of January 1, 2020 to August 31, 2020, FDA has automatically granted a six-month extension (from the FDA recommended 14-month timeframe) to complete the survey. A request for an extension does not need to be filed with FDA or SIA.

Stereotactic – continuing experience effective until 12/31/2021

The SIA is allowing the following options for a physician or technologist to meet the stereotactic continuing experience through 12/31/2021. A total of 12 total breast biopsy procedures must be met for each calendar year with at least 6 being stereotactic breast biopsies. The remaining 6 can be any combination of the following and demonstration of the chosen combination needs to be clearly documented.

1. Stereotactic breast biopsy procedures
2. Stereotactic biopsy of a breast phantom with documentation of steps taken or written report
3. Stereotactic breast biopsy case review – must be documented and include:
 - a. Pre-biopsy mammographic examination was reviewed
 - b. Scout and stereotactic images were appropriately positioned
 - c. Biopsy needle pre-fire and post-fire exam demonstrate appropriate positioning and targeting
 - d. Specimen radiograph demonstrates sampling the area of concern
 - e. Post biopsy exam shows a biopsy marker in appropriate placement
 - f. Post biopsy mammogram demonstrates appropriate biopsy marker positioning
 - g. Review of post biopsy pathology shows concordance of findings with appropriate follow up recommendations
4. Mammographic guided wire localization procedure
5. Ultrasound guided breast biopsy procedure
6. MRI guided breast biopsy procedure

The above temporary option will allow physicians and technologist to achieve continuing experience due to the possible significant decrease in patient volume. This is in lieu of all 12 procedures being stereotactic breast biopsies.



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